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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,948	01/30/2004	Helena Gyback	085747-0315	2491

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EXAMINER	
TUCKER, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1624	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/766,948	GYBACK ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 18Aug04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to chemical compounds of formula I, classified in class/subclasses 544/349, 350 and 353

II. Claims 14-24, drawn to a method of treatment, a pharmaceutical composition, and a "use," classified in class/subclass 514/249.

III. Claim 25, drawn to a process for the preparation of the compound according to claim 1 or 2, classified in class/subclasses 544/349, 350 and 353.

IV. Claims 26-28, drawn to a variety of intermediate compounds employed in preparation of formula I compounds and others, classified in classes 544, 564 and 556, various subclasses.

The inventions are distinct, each from the other because:

Inventions I and II are related as product (Group I),process of use, and sub-product (Group II). The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case conditions treatable with Group I compounds are treatable with materially different compounds. Treatment of neurological disorders is cited as one of the preferred utilities of the compounds of the invention in the instant specification on page 16. Neurological disorders, as applicants are aware, are treated with myriad products

which are materially different than Group I compounds. Additionally, the pharmaceutical composition included in Group II is not the sole manner in which Group I compounds could be made into a sub-product. Compounds from Group I could be employed in manufacturing laboratory analytical reagents, for identification of mGluR receptors, as taught on page 17 of the specification. Such a reagent composition would not be a pharmaceutical composition. Finally, the distinction between Groups I and II is evident from the separate classification of the two.

Inventions I and III are related as product and process of making the product. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case products in Group I could be produced by a materially different process, such as one where a quinoxaline moiety is subjected to a Friedel-Crafts type acylation.

Inventions I and IV are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate products are useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate products are deemed to be useful as intermediates for making compounds other than Group I compounds and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. The Group IV compounds and Group I compounds are patentably distinct as

well. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between compounds, pharmaceutical compositions, and method of use claims. Where applicant elects claims directed to compounds, and a compound claim is subsequently found allowable, withdrawn pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the allowable compound claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Pharmaceutical composition claims and method of use claims that depend from or otherwise include all the limitations of the patentable compound** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the compound claims and the rejoined pharmaceutical composition claims and method of use claims will be withdrawn, and the rejoined pharmaceutical composition and method of use claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected compound claim is found allowable, an otherwise proper restriction requirement between compound claims, pharmaceutical composition claims and method of use claims may be maintained. Withdrawn pharmaceutical composition claims and method of use claims that are not commensurate in scope with an allowed compound claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the pharmaceutical composition claims and method of use claims should be amended during prosecution either to maintain dependency on the compound claims or to otherwise include the limitations of the compound claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Comments

The last two named compounds in claim 27 are the same as the two compounds named in claim 26.

At such time of rejoinder of the pharmaceutical composition claims and method-of-use claims, method-of-use claims will be the subject of a rejection under the first paragraph of 35 U.S.C. 112, for lack of an enabling disclosure. As a starting point from which to gauge what was known by those of ordinary skill about the therapeutic application of mGluR antagonists at the time the invention was made, the examiner submits herewith, a copy of the following reference:

> Ritzén et al, "Molecular Pharmacology and Therapeutic Prostpects of Metabotropic Glutamate Receptor Allosteric Modulators" *Basic & Clinical Pharmacology & Toxicology*, vol. 97, pages 202-213 (2005).

The reference was published after the instantly claimed subject matter was conceived, but discusses some what was known at and around that time. In October of 2005, when the reference was published, there was still a dearth of knowledge insofar as the therapeutic application of mGluR antagonists was concerned (see pages 208-211).

Claim 18 is not patentable under 35 U.S.C. 101, it is a "use" claim.

Claims 15-17 and 19-23 are substantial duplicates. The intended use limitation on those claims does not further limit the claim from which they depend.

The preceding statements should not indicate in any way to applicants that any claim has been examined, even in part, the examiner is merely offering these comments

as a courtesy, and pursuant to the instructions found in the MPEP to examiners in making Requirements for Restriction, in chapter 814.

Conclusion

Any inquiry concerning this communication should be directed to Zachary Tucker whose telephone number is (571) 272-0677. The examiner can normally be reached Tuesday-Thursday from 8:00am to 4:30pm or Monday from 6:00am to 1:30pm. If Attempts to reach the examiner are unsuccessful, contact the examiner's supervisor, James O. Wilson, at (571) 272-0661.

The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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